PATENT
930008-2003

REMARKS

Reconsideration and withdrawal of the requirement for restriction and election of species are respectfully requested in view of the amendment and remarks herewith, which place the application into condition for allowance.

Claims 3-14 and 24-51 are now pending. Claims 10-14 and 24-27 and 30-33 are amended, claims 1, 2, and 16-23 are cancelled and new claims 34-51 are added. No new matter is added.

It is submitted that the claims, herewith and as originally presented, are in full compliance with the requirements of 35 U.S.C. §112. The additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, the additions, support for which is found throughout the specification and from the pending claims, are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

Pursuant to 37 C.F.R. § 1.136(a), Applicants respectfully petition the Assistant Commissioner for Patents to extend the time period for responding to the outstanding Office Action (Restriction Requirement) of October 1, 2001, up to and including December 1, 2001, which is a Saturday, therefore up to and including Monday December 3, 2001 ($ 55.00). Should any additional fee be required for the consideration of this Response, the Assistant Commissioner is authorized to charge such fee against, or credit any overpayment to, Deposit Account No. 50-0320.

The October 1, 2001 Office Action required an election under 35 U.S.C. § 121 and 372 from:

Group I. Claims 1-14 and 22-33, drawn to a nucleic acid and kit.

Group II. Claims 15-21, drawn to an amplification method.

Group I, claims 1-14 and 24-33, and the species of SEQ ID NO:1 as recited in claims 3-6 and 24-27 are elected, with traverse, for further prosecution in this application. The traverse is as follows:

It is respectfully requested, for the following reasons, that the restriction requirement be reconsidered and withdrawn and that the Examiner conduct a complete search, examination and prosecution of the subject matter claimed in Groups I and II—as they all relate to a single inventive concept, i.e., there is unity of invention, and there is no undue or serious burden in searching and examining all of the claims of Groups I and II.

The Examiner contends that the inventions listed as Groups I and II do not relate to a single inventive concept under PCT rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. More specifically, it is asserted that a nucleic acid molecule that hybridizes to a RNA or DNA of a group of bacteria of the genus *Staphylococcus* is known and characterized. The Examiner cites Milliman (U.S. Pat. No. 5,582,975) as allegedly teaching nucleic acid molecules having 10 nucleotides in length that hybridizes to regions of *Staphylococcus aureus*. Applicants respectfully submit that cancellation of claims 1, 2, 22 and 23 have rendered the assertion by the Examiner that the pending claims lack special technical features moot i.e., the teachings of Millman do not meet the requirements of the pending claims.

Under 35 U.S.C. § 121, if there are two or more independent and distinct inventions in one application, the application may be restricted to one of the inventions. Inventions are "independent" if there are no distinct relationships between two, even with patentably distinct inventions, restriction is not required unless one of the following is present (MPEP 808.02):

1 Separate classification;

2. Separate status in the art; or

3. Different field of search.

Under Patent Office examining procedures, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803) (emphasis added).

Further, to search or examine these groups together does not pose a serious burden on the Examiner. It is respectfully submitted that any search of a nucleic acid molecule or a kit of the Group I claims, i.e., any search of the elected Group I subject matter, will encompass the method of detecting the presence or absence of bacteria of the genus *Staphylococcus* by PCR or nucleic acid hybridization of Group II claims. That is, there is no serious burden to search and to examine Groups I and II as the search and examination of Group I will encompass the subject matter of Group II.

Clearly, the subject matter of Groups I and II have unity of invention and should be searched and examined together in this application. Applicants respectfully assert that the claims directed to a kit have been grouped together in group I because there unity of invention within this group; it is not seen why the method claims have been restricted into a separate group because they can easily be searched and examined without any serious or undue burden on the

Examiner. Accordingly, it is respectfully requested that the restriction requirement be reformulated so that Groups I and II, are searched and examined together in this application.

In sum, Groups I and II can be searched and examined in this application as there is no undue or serious burden in searching and examining these claims together; and, there is clearly unity of invention between Groups I and II. Thus, the restriction requirement is improper and should be reconsidered and withdrawn so that Groups I and II are searched and examined together in this application.

With regard to the requirement for an election of species. Applicants elect, with traverse, for further prosecution SEQ ID NO: 1, recited in claims 3-5 and 24-27, it is understood that the Examiner can broaden the search to include other species, e.g., upon determining that a species is allowable, or as discussed herein, when there is a relationship among the species and/or number of species is not too great. It is respectfully requested that the species election requests be reconsidered and withdrawn, in their entirety.

In this regard, the Examiner is respectfully requested to review M.P.E.P. § 808.01(a) which states that "where there is no disclosure of relationship between species (*see* M.P.E.P. §806.04 (b)), they are independent inventions and election of one invention" is required (July 1998). In view of M.P.E.P. §803, however, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate.

The species of SEQ ID NOs: 1-5 and 6-19 are not too great in number; they can be searched without serious burden. Therefore the request for election should be withdrawn.

In addition, it is respectfully asserted that calling for a Restriction Requirement and an election of species as suggested in the Office Action, constitutes an undue burden to Applicants as well as the public. Hence, they are against public policy. If followed, the Restriction Requirement and the election of species requirement would require Applicants to file numerous additional applications depending on how the Examiner maintains these requirements. The cost of prosecuting and maintaining numerous additional patents is unreasonable in view of the fact that the application as filed includes claims that are all related to one another. Further, under GATT, the period of exclusivity for any patents which issue from these divisional applications is greatly reduced.

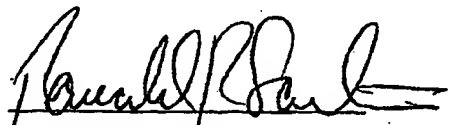
Accordingly, Applicants respectfully maintain that given the absence of serious burden on the Examiner in examining the claims and claimed subject matter and the significant

negative consequences to the Applicants and the public in having the claims examined separately, and the fact that the election of species requirements are contrary to the law and the MPEP, especially since there are linking claims and the number of species is minimal, it is respectfully requested that the Restriction Requirement and the election of species requirements be reconsidered and withdrawn and that all of the claims and all of the claimed subject matter be examined in this one application.

The Examiner contends that Applicants have claims drawn to regions of a nucleic acid sequences that are not identified by SEQ ID NOs:. Claims 1, 2, 22 and 23 have been cancelled rendering this rejection moot and hence also rendering the requirement for a sequence listing moot.

In view of the above, reconsideration and withdrawal of the Requirement for Restriction or an election of species or a reformulation of the groups, are respectfully requested.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: 

Ronald R. Santucci
Reg. No. 28,988
(212) 588-0800

APPENDIX (claims with markings):

10. (Once Amended) Kit according to claim 9, [***characterised*** in that] wherein the nucleic acid molecule is from 10 to 250, preferably from 15 to 30, nucleotides long, especially characterized in that it is the nucleic acid molecule having the sequence SEQ ID NO 5.

11. (Twice Amended) Kit according to claim 1, [***characterised*** in that] wherein the nucleic acid molecule is single-stranded or double-stranded.

12. (Twice Amended) Kit according to claim 1,[***characterised*** in that] wherein the nucleic acid molecule is present

(i) as DNA, or

(ii) as RNA corresponding to (i), or

(iii) as PNA,

the nucleic acid molecule, where appropriate, being modified in a manner known *per se* for analytical detection methods, especially methods based on hybridisation and/or amplification.

13. (Once Amended) Kit according to claim 12, [***characterised*** in that] wherein the nucleic acid molecule is modified by the replacement of up to 10% of the nucleotides, especially 1 or 2 nucleotides, by analogous components known *per se* for probes and/or primers, especially by nucleotides that do not occur naturally in bacteria.

14. (Twice Amended) Kit according to claim 12, [***characterised*** in that] wherein the nucleic acid molecule is modified or labelled or is additionally modified or labelled in that it comprises, in a manner known *per se* for analytical detection methods, one or more radioactive groups, coloured groups, fluorescent groups, groups for immobilisation on a solid phase and/or groups for an indirect or direct reaction, especially an enzymatic reaction, especially using antibodies, antigens, enzymes and/or substances having an affinity for enzymes or enzyme complexes, or it comprises, in a manner known *per se* for analytical detection methods, groups that have been modified or that modify in some other manner.

24. (Once Amended) Nucleic acid molecule that hybridises selectively to RNA or DNA of a group of bacteria of the genus *Staphylococcus*, [***characterised*** in that] wherein it contains at least 10 successive nucleotides of the region from

(i) nucleotide position 54 to 83 of SEQ ID NO 1, or

(ii) nucleotide position 100 to 166 of SEQ ID NO 1, or

(iii) the sequences complementary to (i) or (ii), excluding a nucleic acid molecule that has a sequence according to Figures 1 to 10.

25. (Once Amended) Nucleic acid molecule for the detection of the presence or absence of bacteria belonging to a group of bacteria of the genus *Staphylococcus*, [***characterised*** in that] wherein it makes it possible by means of nucleic acid hybridisation and/or nucleic acid amplification methods under suitable reaction conditions to distinguish between bacteria to be detected and bacteria that are not to be detected and that the distinction is possible by virtue of a differing nucleic acid sequence at at least one base position in the region of SEQ ID NO: 1; or of its complementary sequence, in the genomic DNA and/or RNA of bacteria to be detected and bacteria that are not to be detected, excluding a nucleic acid molecule that has a sequence according to Figures 1 to 10.

26. (Once Amended) Nucleic acid molecule for the detection of the presence or absence of bacteria belonging to a group of bacteria of the genus *Staphylococcus*, [***characterised*** in that] wherein it makes it possible by means of nucleic acid hybridisation and/or nucleic acid amplification methods under reaction conditions known *per se* to distinguish between bacteria to be detected and bacteria that are not to be detected and that the distinction is possible by virtue of a differing nucleic acid sequence at at least one base position in

(i) the region 54 to 83 of SEQ ID NO 1, or

(ii) the region 100 to 166 of SEQ ID NO 1, or

(iii) the sequence that is complementary to (i) or (ii), in the genomic DNA and/or RNA of bacteria to be detected and bacteria that are not to be detected, excluding a nucleic acid molecule that has a sequence according to Figures 1 to 10.

27. (Once Amended) Nucleic acid molecule, [***characterised*** in that] wherein it has the SEQ ID NO 1 or its complementary sequence.

30. (Twice Amended) Nucleic acid molecule, [***characterised*** in that in respect of] wherein its sequence in at least 10 successive nucleotides of its nucleotide chain

(i) [it] is identical to a nucleic acid molecule according to claim 22, or

(ii) [it] corresponds in 9 out of 10 successive nucleotides to a nucleic acid molecule according to claim 22, or

(iii) [it] corresponds in 8 out of 10 successive nucleotides to a nucleic acid molecule according to claim 22, or

(iv) [it] is at least 90% homologous to a nucleic acid molecule according to claim 22.

31. (Once Amended) Nucleic acid molecule, [***characterised*** in that] wherein it has the SEQ ID NO 5 or its complementary sequence.

32. (Twice Amended) Nucleic acid molecule according to claim 22 [***characterised*** in that] wherein it is from 10 to 250, preferably from 15 to 30, nucleotides long.

33. (Twice Amended) Nucleic acid molecule according to claim 22, [***characterised*** in that] wherein the nucleic acid molecule is single-stranded or double-stranded.